II. REMARKS

This response is timely filed as it is accompanied by a petition for an extension of time to file in the third month and the requisite fee.

Attached is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Appendix is captioned **"Version with markings to show changes made"**.

In the outstanding official action the examiner rejected claim 19 under 35 U.S.C. §112, second paragraph as allegedly being indefinite with respect to use of the language "inhibition of action of natural LH is caused by Cetrorelix." In response, the applicants submit that this rejection is now moot. Specifically, the aforementioned language has been replaced with "suppression of the endogenous LH is caused by Cetrorelix." The applicants In view of the foregoing, the applicants request the withdrawal of the rejection of claim 19 based upon 35 U.S.C. §112, second paragraph.

Also in the outstanding official action, the examiner objected to a minor informality with respect to use of the term "being" in claim 18. By the foregoing amendment, the applicants have corrected this informality and therefore request that this objection of claim 18 be withdrawn.

The examiner has maintained the rejection of claims 15, 16, 18-24, 26-37 under 35 U.S.C. §103(a) as being unpatentable over Diedrich et al. in view of Felberbaum et al., and rejected claims 21, 22 and 33 as being anticipated by Diedrich et al. under 35 U.S.C. §102(b). The applicants traverse.

The claimed invention is an improved method of treating infertility disorders, comprising administering an LH-RH antagonist within a controlled ovarian stimulation program either in a single or dual dose regimen of 1 to 10 mg, or in a multiple dosage

regimen of 0.1 to 0.5 mg per day. In particular, preferably a single or dual dose posology, including 2-6 mg, and most preferably 3 mg Cetrorelix on cycle day 6 is used. A preferred multiple dose posology representing a dose of 0.1-0.5, preferably 0.25 mg Cetrorelix also on cycle day 6 may be utilized. In the Felderbaum article, Cetrorelix is administered on day 7 in a dosage of 3 mg or 1 mg daily up to ovulation, which reflects a much higher multiple dosage than is claimed. The low dosages of LH-RH Antagonist recited in the claimed method permit the timing of ovulation to be manipulated within a normal cycle, as opposed to an exogenous gonadotropin-stimulated cycle, without affecting the viability of the growing follicle.

The applicants respectfully submit that this is a remarkable difference in dose and management of IVF therapy. FSH levels in the protocol of Diedrich were suppressed during treatment with Cetrorelix, albeit to a lesser extent than in previously known protocols. Diedrich acknowledged uncertainty regarding the affects of the treatment disclosed therein on FSH levels. Previously used approaches, such as in Felderbaum, did not contemplate the use of the claimed multiple dose posology representing a dose of 0.1-0.5, preferably 0.25 mg Cetrorelix. Felderbaum did not recognize the importance of maintaining FSH secretion at natural levels, and thus fails to suggest a dose of LH-RH antagonist capable of suppressing LH without affecting FSH secretion. Thus, neither Diedrich nor Felderbaum provide motivation to utilize the claimed dosages of LH-RH antagonist while maintaining FSH secretion at a normal level.

Therefore, it is respectfully submitted that Diedrich, either alone or in combination with the Felderbaum reference would not result in the claimed invention. Accordingly, withdrawal of the rejections based upon 35 U.S.C. §§102(b) 103(a) is respectfully requested.

Respectfully submitted,

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Enclosure: Appendix

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claims 18 and 19 are amended as follows:

18. (Three Times Amended) In a method of treating infertility disorders by administering an LH-RH Antagonist and inducing follicle growth by administration of exogenous gonadotropin, the improvement [being] comprising administering an amount of LH-RH [Antagonist] antagonist sufficient to suppress only endogenous LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected, wherein suppression of endogenous LH activity is followed by maintenance of follicle development by endogenous gonadotropins without external stimulation.

19. (Three Times Amended) The method according to claim 18, wherein [inhibition of action of natural] suppression of the endogenous LH is caused by Cetrorelix.

End of Appendix